

TRANSLATION

## PATENT COOPERATION TREATY

## PCT

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference NF20040003		FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/CN2004/001064		International filing date (day/month/year) 20. Sep. 2004 (20. 09. 2004)	Priority date (day/month/year) 26. Sep. 2003 (26. 09. 2003)
International Patent Classification (IPC) or national classification and IPC  <i>see Supplemental Box</i>			
Applicant LI Guoqiao, SONG Jianping			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of <u>2</u> sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input checked="" type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 04.Jul.2005 (04.07.2005)		Date of completion of this report 13.Feb.2006 (13.02.2006)	
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Form PCT/IPEA/409 (cover sheet) (April 2005)

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/CN2004/001064

## Box No. I Basis of the report

## 1. With regard to the language, this report is based on:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into \_\_\_\_\_, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rules 12.3(a) and 23.1(b))
- ☐ publication of the international application (Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

## 2. With regard to the elements of the international application, this report is based on (replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):

- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages \_\_\_\_\_ as originally filed/furnished
- pages \* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages \* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the claims:
- pages \_\_\_\_\_ as originally filed/furnished
- pages \* \_\_\_\_\_ as amended (together with any statement) under Article 19
- pages \* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages \* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the drawings:
- pages \_\_\_\_\_ as originally filed/furnished
- pages \* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- pages \* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (specify): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (specify): \_\_\_\_\_

4. ☒ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☒ the description, pages 1
- ☒ the claims, Nos. 1, 2
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (specify): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (specify): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.  
PCT/CN2004/001064Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability;  
citations and explanations supporting such statement

## 1. Statement:

Novelty (N)	Claims	2	YES
	Claims	1	NO
Inventive step (IS)	Claims	1,2	YES
	Claims	none	NO
Industrial applicability (IA)	Claims	1,2	YES
	Claims	none	NO

## 2. Citations and explanations (Rule 70.7)

D1: CN,A,1305810

Claim 1 lacks novelty over D1. D1 disclosed a pharmaceutical composition composed of dihydroartemisinin (1 part) and piperazine (6 parts), wherein dihydroartemisinin may be replaced by the analogue thereof, i.e. artemisinin, and the composition may be in the forms of tablets, suppositories, granules and injections (see D1 claims 1-3, specification P.2, L.9-12). Thus, the larger scope of claim 1 lacks novelty (Article 33(2) PCT).

The smaller scope of claim 1 is novel (Article 33(2) PCT). The smaller scope of claim 1 and claim 2 fulfill novelty and inventive steps, since the prior arts don't disclose them and they are not obvious (Article 33(3) PCT).

The claims 1-2 are industrially applicable and meet the criteria set out in PCT Article 33(4).

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## Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

There are two different scopes in claim 1, thus claim 1 is not clear (Article 6 PCT). The smaller scope of claim 1 is not within the larger scope of claim 1, i.e. the number 0.6 is not within 0-0.2, thus claim 1 is not clear, too (Article 6 PCT).

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## Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

The amendments filed with the letter dated on 04. Jul. 2005 introduce subject-matters which extends beyond the content of the application as filed and contrary to Article 34(2)(b)PCT, because the specific numbers such as piperazine 5 parts and primaquine 0-0.05 parts are not disclosed in the application as filed. Although the numbers are within the scope as filed, the amendments extend beyond the content of the application as filed.

A61K 31/336 (2006.01) i

A61K 31/496 (2006.01) i

A61K 31/4706 (2006.01) i

A61P 33/06 (2006.01) i